

Reconsideration of the above-identified application is respectfully requested in view of the following amendments and remarks.

### **REMARKS**

#### ***Status of the Claims***

Claims 17-29 are currently pending. Claims 17-29 have been rejected.

Claims 17 and 19 have been amended. Support for the amendments to claims 17 and 19 can be found, *inter alia*, in the specification at page 13, lines 17-20.

Claims 26-29 have been cancelled.

No new matter has been added.

#### ***Rejections under 35 U.S.C. § 102***

The Examiner has rejected claims 17-21, 23, 25, 26 and 29 under 35 U.S.C. §102(e) as being anticipated by Youssefyeh et al. (U.S. Pat. No. 5,968,519). Applicants respectfully traverse this rejection.

#### **Claim 17**

In the interest of expediting prosecution Applicant has amended claim 17. As amended, claim 17 is directed to, “[a] method of treating immunological skin disorders comprising applying onto an area of skin affected by said skin disorder a fluid, film-forming carrier having contained therein a steroid, and hardening the carrier into a tangible, member juxtaposed to said affected area, wherein said film-forming carrier is nitrocellulose.” See claim 17, as currently amended (emphasis added). Applicant respectfully asserts that Youssefyeh et al. does not teach or disclose the use of nitrocellulose as a film-forming carrier, and thus, does not disclose

all the claim limitations of the presently claimed invention. To anticipate a claim, a reference must teach every element of the claim. See M.P.E.P. § 2131, Eighth Edition, Rev. Aug. 2006 at page 2100-67 (emphasis added).

According to the Examiner, Youssefyeh et al. teaches a “method of treating for the relief of inflammation and/or pain associated with inflammatory dermatoses such as eczema, urticaria, psoriasis and the like comprises topically administering a therapeutically effective amount of a finely divided powder of safflower seed or its extract sufficient to induce alleviation of signs, symptoms, or causes of inflammation or pain in a pharmaceutically acceptable carrier.” See Office Action at page 3. The Examiner further points out, “[a] preferred form of topical delivery is film-forming materials loaded with finely divided powder or safflower seed or its extract.” See Office Action at page 4, first paragraph. The Examiner further points out that Youssefyeh et al. discloses useful film-forming materials include cellulosic derivatives, such as methylcellulose, hydroxyethyl cellulose, hydroxypropyl cellulose and other synthetic polymers. See Office Action at page 4, first paragraph; see also Youssefyeh et al. at col. 16, lines 65-67. However, Applicant respectfully points out that Youssefyeh et al. does not teach or disclose the use of nitrocellulose as the film-forming carrier. As such, Applicant respectfully asserts that Youssefyeh et al does not teach or discloses all the claim limitations of the presently claimed invention, and thus, does not anticipate the presently claimed invention.

Moreover, Applicant submits herewith the Declaration of Joel R. Studin under 37 U.S.C. §1.132 along with Exhibit A, showing a comparison of transdermal effectiveness evaluation of various possible film-forming carriers for delivering topical treatments such as corticosteroids. As pointed out in the Declaration, transdermal effectiveness was determined by the well-known McKenzie-Stoughton

vasoconstriction assay, a blanching assay which results in a localized whitening of the spot where hydrocortisone is adsorbed into the skin. The more hydrocortisone that was adsorbed into the skin, the whiter the localized spot appeared. See paragraph 6 of the Declaration. As such, the McKenzie-Stoughton test was used to determine which carrier resulted in the best adsorption of hydrocortisone into the skin. In accordance with this assay, a blanching score was determined for each of the carriers tested by three different observers, at different time points (1-, 2-, and 4-hours), on four test subjects. These scores were added up to give a total blanching score. The higher the score, the higher the level of blanching, and thus, the higher the level of hydrocortisone adsorbed into the skin. See paragraph 6 of the Declaration.

The blanching scores were as follows, methyl cellulose (14), hydroxymethylcellulose (25), nitrocellulose (flexible collodion) (141), nitrocellulose (flexible collodion/xanthan gum) (59), hydroxyethylcellulose (29), cellulose acetate (23), propylene glycol (7), aluminum hydroxide (49) and tragacanth (3). See the Declaration at paragraphs 8 and 9. Nitrocellulose (Flexible Collodion) had the highest blanching test score of 141, and nitrocellulose (flexible collodion/xanthan gum) has the second highest test score with a 59. Again, the higher the score, the higher the degree of blanching, and thus, the highest degree of transdermal transmission of the active agent (hydrocortisone) tested. See Declaration paragraph 8; see also Exhibit A at page 6. The Examiner is kindly directed to the bottom of page 6 of Exhibit A, which states, “[m]ost carriers showed very poor transdermal transmission of the active. Nitrocellulose however, showed a very strong transmission in our formulation... [i]t is our suggestion that you continue the development of your products using the nitrocellulose base that you suggested.” See also, the Declaration at paragraph 8.

Furthermore, Applicant respectfully points out that Exhibit A and the Declaration submitted, tested two of the film-forming carriers specifically disclosed in Youssefyeh et al., methylcellulose and hydroxyethyl cellulose. Applicant further notes that blanching scores for each, 14 and 29, respectfully, and thus, the level of hydrocortisone adsorbed into the skin were significantly less than that seen for nitrocellulose. Therefore, Applicant respectfully asserts that use of nitrocellulose as the film-forming carrier shows a superior level of blanching of hydrocortisone into the skin when compared to other film-forming cellulose carriers.

As such, Applicant respectfully asserts that Youssefyeh et al. does not and cannot anticipate claim 17, or claim 18, which depends therefrom. Reconsideration and withdrawal of this rejection are respectfully requested.

#### Claim 19

Like claim 1, claim 19 has been amended to recite, “[a] composition for treating adverse skin conditions comprising a fluid, film-forming carrier and an active ingredient comprising a topically active steroid or, a silicone-gel or mixture thereof, said carrier capable of hardening to a tangible member, wherein said film-forming carrier is nitrocellulose.” See claim 19, as currently amended (emphasis added).

As Applicant has pointed out hereinabove, Youssefyeh et al. does not teach or disclose the use of nitrocellulose as the film-forming carrier, and thus, Youssefyeh et al. does not and cannot anticipate the presently claimed invention. To anticipate a claim, a reference must teach every element of the claim. See M.P.E.P. § 2131, Eighth Edition, Rev. Aug. 2006 at page 2100-67 (emphasis added).

Furthermore, as noted hereinabove, Applicant has submitted the Declaration of Joel Studin under 37 U.S.C. § 1.132 along with Exhibit A, showing a comparison of

transdermal effectiveness evaluation of various possible film-forming carriers for delivering topical treatments such as corticosteroids. Nitrocellulose (Flexible Collodion) had the highest blanching test score of 141, and nitrocellulose (flexible collodion/xanthan gum) has the second highest test score with a 59. Again, the higher the score, the higher the degree of blanching, and thus, the highest degree of transdermal transmission of the active agent (hydrocortisone) tested. See Declaration paragraph 8; see also Exhibit A at page 6. The Examiner is kindly directed to the bottom of page 6 of Exhibit A, which states, “[m]ost carriers showed very poor transdermal transmission of the active. Nitrocellulose however, showed a very strong transmission in our formulation... [i]t is our suggestion that you continue the development of your products using the nitrocellulose base that you suggested.”

Again, Applicant respectfully points out that Exhibit A and the Declaration submitted, tested two of the film-forming carriers specifically disclosed in Youssefyeh et al., methylcellulose and hydroxyethyl cellulose. Applicant further notes that blanching scores for each, 14 and 29, respectfully, and thus, the level of hydrocortisone adsorbed into the skin were significantly less than that seen for nitrocellulose. Therefore, Applicant respectfully asserts that use of nitrocellulose as the film-forming carrier shows a superior level of blanching of hydrocortisone into the skin when compared to other film-forming cellulose carriers.

As such, Applicant respectfully asserts that Youssefyeh et al. does not and cannot anticipate claim 19, or claims 20-21, 23, 25, 26 and 29, which depend therefrom. Reconsideration and withdrawal of this rejection are respectfully requested.

***Rejections under 35 U.S.C. § 103***

The Examiner has rejected claims 17, 19-21 and 23-29 under 35 U.S.C. §103(a) as being unpatentable over Youssefyeh et al. (U.S. Pat. No. 5,968,519) in view of Herb et al. (U.S. Pat. No. 5,534,246). Applicant respectfully traverses this rejection.

As previously pointed out hereinabove, Applicant has amended independent claims 17 and 19 to recite, “wherein said film-forming carrier is nitrocellulose.” See claims 17 and 19, as currently amended (emphasis added). It is well established that to render a claimed invention obvious all the claim limitations must be taught or suggested by the prior art. As Applicant has previously pointed out, although Youssefyeh et al. discloses the use of a film-forming carrier, Youssefyeh et al. does not disclose the use of nitrocellulose as a film-forming carrier.

The Examiner cites Herb to overcome the deficiencies of Youssefyeh et al. More specifically, according to the Examiner, “Herb et al. also teaches that nonvolatile organic compounds, such as phenyltrimethicone can also be added to the compositions to provide an aesthetic effect of for adjusting the refractive index.” See Office Action at page 7. However, like Youssefyeh et al., Herb et al. does not disclose the use of nitrocellulose as a film-forming carrier, and thus, the combination of Youssefyeh et al. with Herb et al. does not disclose all the claim limitations of the presently claimed invention.

Again, Applicant has submitted the Declaration of Joel Studin under 37 U.S.C. §1.132 along with Exhibit A, showing a comparison of transdermal effectiveness evaluation of various possible film-forming carriers for delivering topical treatments such as corticosteroids. Nitrocellulose (Flexible Collodion) had the highest blanching test score of 141, and nitrocellulose (flexible collodion/xanthan gum) has the second

highest test score with a 59. Again, the higher the score, the higher the degree of blanching, and thus, the highest degree of transdermal transmission of the active agent (hydrocortisone) tested. See Declaration paragraph 8; see also Exhibit A at page 6. The Examiner is kindly directed to the bottom of page 6 of Exhibit A, which states, “[m]ost carriers showed very poor transdermal transmission of the active. Nitrocellulose however, showed a very strong transmission in our formulation... [i]t is our suggestion that you continue the development of your products using the nitrocellulose base that you suggested.”

Furthermore, Applicant respectfully points out that Exhibit A and the Declaration submitted, tested two of the film-forming carriers specifically disclosed in Youssefyeh et al., methylcellulose and hydroxyethyl cellulose. Applicant further notes that blanching scores for each, 14 and 29, respectfully, and thus, the level of hydrocortisone adsorbed into the skin were significantly less than that seen for nitrocellulose. Therefore, Applicant respectfully asserts that use of nitrocellulose as the film-forming carrier shows a superior level of blanching of hydrocortisone into the skin when compared to other film-forming cellulose carriers.

As such, Applicant respectfully asserts that the combination of Youssefyeh et al. with Herb et al. does not and cannot render claims 17, 19-21 and 23-29 obvious. Reconsideration and withdrawal of this rejection is respectfully requested.

The Examiner has rejected claims 17-29 under 35 U.S.C. §103(a) as being unpatentable over Mantelle (U.S. Pat. No. 5,446,070) in further view of Herb et al. (U.S. Pat. No. 5,534,246). Applicant respectfully traverses this rejection.

As previously pointed out hereinabove, Applicant has amended independent claims 17 and 19 to recite, “wherein said film-forming carrier is nitrocellulose.” See

claims 17 and 19, as currently amended (emphasis added). According to Mantelle, “[s]uitable adhesive carriers include... cellulose, and cellulose derivatives such as methyl cellulose, propyl cellulose, cellulose acetate and the like.” See Mantelle at col. 12, lines 55-65. However, Applicant respectfully asserts that Mantelle does not disclose the use of nitrocellulose as a film-forming carrier.

The Examiner cites Herb to overcome the deficiencies of Mantelle. More specifically, according to the Examiner, “Herb et al. also teaches that nonvolatile organic compounds, such as phenyltrimethicone can also be added to the compositions to provide an aesthetic effect of for adjusting the refractive index.” See Office Action at page 7. However, like Mantelle, Herb et al. does not disclose the use of nitrocellulose as a film-forming carrier, and thus, the combination of Mantelle with Herb et al. does not disclose all the claim limitations of the presently claimed invention.

Again, Applicant respectfully directs the Examiner’s attention to the Rule 132 Declaration of Joel Studin. As previously pointed out, according to the bottom of page 6 of Exhibit A, “[m]ost carriers showed very poor transdermal transmission of the active. Nitrocellulose however, showed a very strong transmission in our formulation... [i]t is our suggestion that you continue the development of your products using the nitrocellulose base that you suggested.”

Furthermore, Applicant respectfully points out that two of the cellulose derivatives disclosed in Mantelle, methyl cellulose and cellulose acetate, were tested. Applicant further notes that blanching scores for each, 14 and 23, respectfully, and thus, the level of hydrocortisone adsorbed into the skin were significantly less than that seen for nitrocellulose. Therefore, Applicant respectfully asserts that use of




nitrocellulose as the film-forming carrier shows a superior level of blanching of hydrocortisone into the skin when compared to other film-forming cellulose carriers.

As such, Applicant respectfully asserts that the combination of Mantelle with Herb et al. does not and cannot render claims 17-29 obvious. Reconsideration and withdrawal of this rejection are respectfully requested.

Respectfully submitted,

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